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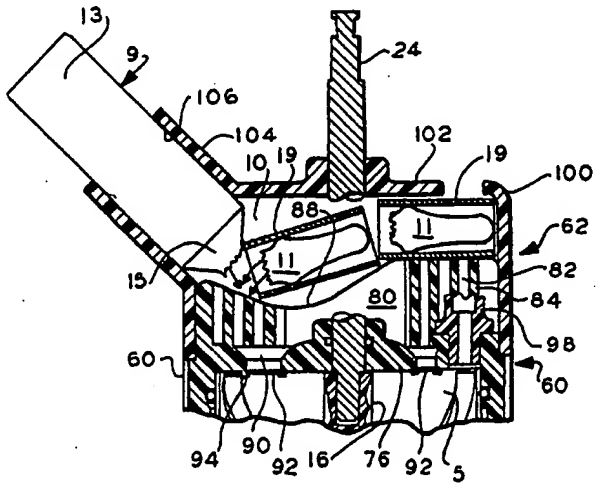

(57) Abstract

A cap includes an intermediate cap (60) and a cover cap (62) permanently secured together forming a cap chamber (10) and enclose the top of a housing (4) bone cement mixing chamber (5). A ribbed (84) contoured camming surface (86) is in the cap chamber (10) against which a received glass vial (9) is forced during insertion, breaking the vial head (11) and emptying the vial contents into the cap chamber (10) and then into the mixing chamber (5) through a fragment filter (92). The filter (92) and the ribbed (84) camming surface (86) traps glass fragments and vial head (11) in the cap chamber (10). The mixing chamber (5) is selectively coupled to an axially displaceable discharge tubular sleeve conduit (38) containing a feed auger (46). The discharge conduit (38) is axially opened to the mixing chamber (5) after completion of the cement liquid–powder mixing by rotating a collar (48) having a helix groove (54) connected to the sleeve (40). Various vial breaking cap embodiments are disclosed.

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BONE CEMENT MIXER AND DISPENSER

This invention relates to devices for mixing two part bone cement components including an aggressive liquid monomer such as methyl methacrylate supplied in frangible glass vials and a polymer powder for surgical applications in securing prosthetic devices to bones and joints and to dispensers for such cement which is an acrylic material.

Of interest is copending application Serial No. 08/752,003 entitled "Integrated Bone Cement Mixing and Dispensing System" filed November 15, 1996 in the name of Donald Barker et al. and incorporated by reference in the entirety herein, the assignee of the present invention having rights in this application.

A cement mixing and dispensing device is disclosed in the aforementioned application. In one device, the components are mixed, entrained air removed, and the mixed cement dispensed without

separate handling. After use, the device is discarded. This device works well, however, it requires the manual insertion of the powder component and the liquid component into the device. To do so, the device has a cover over a mixing chamber. The cover is removed and the liquid and powder are then poured into the mixing chamber.

The problem is that, like all prior art systems employing such liquids and cements, the liquid is aggressive and attacks most containers. As a result, the liquid is packaged and stored in relatively inert glass vials. These vials are frangible. They have a narrowed tapered head connected to a wider body via a reduced diameter neck.

To empty the vial, a nurse in an operating room needs to break open the vial typically by fracturing the head or neck. This is undesirable, as the vial may shatter or, at best, glass fragments can be a problem and must be accounted for and precluded from causing injury. Also, the fractured vial or fragments have sharp edges which undesirably may cut the user or the user's gloves. The vial thus needs to be handled with care and accidents may occur.

In addition, the liquid in the vial has noxious fumes. When the vial is fractured, the fumes escape to the ambient and over long periods of repetitive exposure can be the source of health problems. At best, the fumes are highly unpleasant. In the aforementioned copending application, the fumes are exhausted by a vacuum connected to the mixing device mixing chamber. However, the fumes still escape in a sufficiently large volume to the ambient as the liquid is poured into the mixing device from the fractured vial.

A need is seen by the present inventors for a mixing device for such cement which will address the problems of fumes and broken glass edges and fragments associated with the vial.

A vial fracturing device according to the present invention is for use with a bone cement mixing and dispensing apparatus for mixing liquid with powder cement components, the liquid tending to emit noxious fumes, the apparatus having a component mixing chamber and mixed cement dispensing means coupled to the mixing chamber, the mixing chamber for receiving the powder and the liquid components, the liquid being supplied in a frangible glass vial, the

vial when fractured tending to produce undesirable glass fragments. The device comprises a housing forming a liquid receiving chamber having a discharge port arranged for fluid communication with the mixing chamber; vial receiving means coupled to the housing for receiving and enclosing at least a portion of the vial and for permitting the liquid to flow to and through the discharge port into the mixing chamber from the received vial when fractured; and vial fracturing means coupled to the housing and to the liquid receiving chamber for fracturing the received enclosed vial portion.

In one aspect, means are coupled to the vial receiving means for substantially confining the liquid fumes to the liquid receiving chamber.

In a further aspect, filter means are coupled to the housing for preventing the fragments from discharging through the discharge port.

In a further aspect, the vial receiving means has a vial inlet conduit coupled to the liquid receiving chamber, the liquid receiving chamber for further receiving the vial portion, the fracturing means including contoured surface means in the receiving chamber forming a cam surface for

fracturing the vial upon insertion of the vial into the inlet conduit and upon engagement of the vial portion against the surface.

The vial may have a body connected to a head by a neck, the cam surface for fracturing the neck during insertion to separate the head from the body.

The liquid receiving chamber in a further aspect provides a receptacle for the separated head and fragments.

The vial receiving conduit in a further aspect defines a vial insertion axis, the cam surface being inclined relative to the axis for forcing the head off the axis relative to the body at the neck during the insertion.

In a still further aspect, the liquid receiving chamber provides a receptacle for a plurality of the heads.

The surface means may comprise a plurality of spaced ribs forming a fluid conduit into the mixing chamber.

In a further aspect, the mixing apparatus is included with the device and includes a cover releasably secured to the apparatus for enclosing the apparatus chamber to permit the powder to be inserted

in the mixing chamber, the cover including the device integral therewith and a filter coupled to the discharge port for filtering the glass fragments from entering the apparatus chamber.

In a further aspect, a bone cement mixing and dispensing apparatus for mixing liquid with powder cement components comprises a housing having a component mixing chamber for receiving the powder and the liquid components and mixed cement dispensing means coupled in selective fluid communication with the mixing chamber.

The dispensing means includes an axially displaceable sleeve forming a cement feed conduit and sleeve displacement means rotatably coupled to the housing and having a helical channel engaged with and for displacing the sleeve in response to rotation of the displacement means.

IN THE DRAWING:

FIGURE 1 is a side elevation sectional view of a bone cement mixing and dispensing device according to an embodiment of the present invention prior to insertion of the cement components to be mixed;

FIGURE 2 is a top plan sectional view of the device of Fig. 1;

FIGURE 3 is a further fragmented view similar to that of Fig. 1 showing the initial insertion of the liquid component into the device mixing chamber which contains a powder cement component (not shown) previously inserted;

FIGURE 4 is a view similar to that of Fig. 3 showing a subsequent vial fracturing stage for insertion of the liquid component into the device mixing chamber;

FIGURE 5 is a view similar to that of Fig. 4 showing a subsequent vial fracturing stage for insertion of a second vial of the liquid component into the device mixing chamber;

FIGURE 6 is a view similar to that of Fig. 5 showing the device with the fractured fragments of multiple vials captured in the device fragment receptacle;

FIGURE 7 is a side elevation fragmented sectional elevation view of a mixing and dispensing device according to a second embodiment of the present invention;

FIGURE 8 is a fragmented view similar to that of Fig. 7 showing the fracturing of the liquid component vial;

FIGURES 9, 10 and 11 are fragmented side elevation sectional views of a third embodiment of the present invention showing different successive stages in fracturing the liquid cement component vial for adding the component to the mixing chamber;

FIGURE 12 is a top plan view of a further embodiment of a bone cement mixing and dispensing device according to the present invention;

FIGURE 13 is a sectional side elevation view of the device of Fig. 12 taken along lines 13-13 and further showing a liquid component vial inserted in the device liquid receiving port;

FIGURE 14 is a view similar to the view of Fig. 13 showing a later stage in which the vial is fractured in order to add the liquid component to the device mixing chamber;

FIGURE 15 is a side elevation sectional view of a further embodiment of the present invention; and

FIGURE 16 is a top plan view of the embodiment of Fig. 15 taken along lines 16-16.

In Figs. 1 and 2, device 2 comprises a preferably molded thermoplastic housing 4. The housing 4 has a bone cement mixing chamber 5 containing component mixing assembly 6. The assembly

6 mixes selectively received cement components comprising a bone cement powder (not shown) with a bone cement liquid 7 (Fig. 3) from a glass vial 9 (Fig. 3). The device 2 further includes a cover assembly 8 comprising molded thermoplastic elements forming a glass fragment, vial fragmented head 11 (Fig. 4) and liquid 7 cement component receiving chamber 10. The device 2 dispenses the mixed cement via dispensing assembly 12.

The mixing assembly 6 includes helically extending thermoplastic mixing paddles 14 secured to central shaft 16 which rotates about axis 17. The interior wall 21 of chamber 5 is U-shaped concentric on axis 17. The external edges 18 of the paddles 14 are arcuate and closely engage the wall 16 surface. The paddles 14 terminate at their upper region in a cross member 20, which is optional. The mixing assembly 6 is also described in the aforementioned copending application incorporated by reference herein.

The shaft 16 has an upper central axially extending drive bore 22. A drive shaft 24, e.g., with keyed lower and upper drive ends, e.g.; hex shaped, is rotatably driven by a power source (not

shown). The drive shaft lower end mates in a complementary keyed bore 22 for rotating the paddles 14. The shaft 16 has a lower axially extending cylindrical boss 23. In boss 23 is a central downwardly extending bore 25 in communication with circular cylindrical bore 27 concentric with bore 25. The base of the chamber 5 has central axially extending through bore 26 axially aligned with bore 25 and groove 27.

The housing 4 includes a depending thermoplastic integral one piece molded extension comprising two diametrical opposite spaced apart tips 28 (one being shown). The tips 28 form a support for the dispensing assembly 12 and form two diametrically opposing axially and radially extending slots 30, 30'. The tips 28 form therebetween an axially extending central bore 26' which is coextensive with bore 26 and is in communication with slots 30. The tips 28 have a bottom edge 32 to which nozzle 34 is screwed via flange 36 by screws (not shown). The nozzle 34 has a bone cement dispensing discharge conduit 38.

A cylindrical washer-like preferably metal member 31 is secured in bore 27 to auger 46. Member

31 has a central bore through which the auger 46 shaft 47 passes into engagement with bore 25. An O-ring is in a respective corresponding groove in member 31 radial inner and outer peripheral surfaces. A metal circular cylindrical metal sleeve 29 is attached to the inner bore of an outer thermoplastic circular cylindrical sleeve 40. Sleeve 29 engages the member 31 outer O-ring. Sleeve 29 has an upper radially outwardly extending flange.

Sleeve 40 is located in the bore 27 and includes an O-ring at its upper end captured between the upper end edge and sleeve 29 flange. The latter O-ring is in contact with the bore 27 wall. Sleeve 29 may be pressed into the sleeve 40. The auger 46 and member 31 rotate relative to the metal sleeve 29 and sleeve 40 which do not rotate.

Sleeves 40 and 29 are secured for selective axial downward displacement out of bore 27 on axis 17. The sleeve 40 is slidably sealed to the boss 23 bore 27 by its upper O-ring. The sleeve 40 has an axially depending circular inner cylindrical cement dispensing channel 42 concentric with the axis 17. The sleeve 40 outer peripheral surface is sealed to bore 26 by a second intermediate O-ring in a second

sleeve groove. The second O-ring is axially spaced beneath the upper end O-ring.

The two sleeve 40 O-rings are axially aligned and respectively seal the channel 42 and bore 26 in fluid isolation to the chamber 5. The latter two O-rings confine the cement components to the chamber 5 during mixing.

A pair of diametrically opposite radially outwardly extending circular cylindrical rods form ears 44, 44' and extend from the sleeve 40 radial outer surface. The ears 44 and 44' pass through and axially displace in corresponding respective slots 30, 30'. A third lowermost O-ring is secured to and in a sleeve 40 outer groove at the sleeve 40 lowermost edge. The third O-ring seals the sleeve to the bore 26' at the lowermost sleeve end beneath the ears 44, 44'.

Auger 46 is secured for rotation about the axis 17. The auger 46 is secured at its uppermost end to bore 25 in a complementary keyed arrangement. The other lower auger end is in the nozzle 34 discharge conduit 38. The auger 46 is rotatably driven about axis 17 by the rotation of the shaft 16. The auger feeds mixed cement selectively supplied to channel 42

from chamber 5 to the nozzle 34 cement discharge conduit 38. The cement is fed when the sleeve 40 is in its lowermost position (not shown).

An axially extending cylindrical collar 48 concentric with axis 17 and sleeve 40 is rotatably secured between the nozzle 34 flange 36 and a shoulder 50 at the base of the housing 5 beneath the chamber 5. The collar rotates in abutting relation to the shoulder 50 and nozzle 36 flange surface 52. The collar 48 has an internal helix thread 54. The ears 44, 44' mate with the thread 54. When the collar is manually rotated, the helical thread 54 axially displaces the sleeve 40 downward in direction 56.

In the most downward position (not shown) of the sleeve 40, its uppermost O-ring seats against the bore 26, sealing the chamber 5 from the ambient at the sleeve 40 external surface. In this position, the sleeve upper end is approximately flush with the chamber 5 bottom surface forming a cement receiving port 57 between the boss 23 and chamber 5 bottom surface. The port 57 provides fluid communication between chamber 5 and sleeve channel 42.

A downwardly depending finger 58 is molded thermoplastic material integral one piece with one of the housing tips 28. The finger 58 is located with its tip region in slot 30' which resiliently abuts ear 44' in a direction transverse direction 56. When the sleeve 40 is in its lowermost position (not shown), the ear 44' displaces beneath the depending end of the finger 58. The finger 58 then snaps into its normal quiescent position above the ear 44' in the slot 30' locking the sleeve 40 in this lowermost position, preventing reuse of the device 2.

The cover assembly 8, Figs 1 and 2, comprises a cylindrical intermediate cap 60 and cover cap 62, each being molded thermoplastic. The intermediate cap 60 includes an outer circular skirt cylinder 64 which is threaded to the housing 4 external threads 66 at the housing 4 upper end. An outer shoulder 68 is formed in the upper outer surface of the cylinder 64. The outer surface of the cylinder 64 is formed with serrations 70. An O-ring 72 seals the cylinder 64 to the housing 4.

The cover cap 60 includes a transverse plate member 74 having a planar plate portion 75 and is molded one piece with cylinder 64. A boss 76 is

centrally of the plate member 74 and upstands from plate portion 75. The boss 76 has an axial extending bore 78 that receives drive shaft 24 which passes therethrough. The boss 76 is rotatably sealed to the drive shaft with an O-ring. A camming member 80 is molded integral one piece with cylinder 64 and plate member 74. Camming member 80 upstands relative to the plate member portion 75.

In Fig. 2, camming member 80 in plan view is somewhat kidney shaped extending partially about the boss 76. The member 80 has a plurality of axially extending fluid passages 82 formed by arcuate circular segment ribs 84. The upper surface 86 of camming member 80 is smoothly contoured forming a camming downward and upward ramp surface with a trough 88. The camming member beneath the ribs 84 has a somewhat kidney shaped semicircular segment port 90. Port 90 is in fluid communication with chambers 10 and 5 via the passages 82.

A preferably circular disk or washer-like filter 92, Fig. 1, is secured to the camming member to enclose the port 90. In the alternative, the filter may be somewhat kidney shaped to match the shape of the port 90. The filter 92 has a micromesh pore size

sufficiently large to pass therethrough the monomer liquid mixing component from the vial 9 while capturing and filtering out glass fragments from the liquid. The filter 92 may comprise any known particulate filtering substrate inert to the liquid 7. The glass fragments are retained by the filter 92 in the chamber 10 formed by the caps 60 and 62.

The filter 92 may be secured to the plate member 74 by heat deformation of the plate member 74 into a rib 94. In the alternative, the filter may be bonded by a suitable adhesive or other arrangement. The filter 92 is shown preferably secured by rib 94. In the alternative, the filter may be secured by bonding. This is so that the filter surface in the chamber 5 is flush with upper chamber surface formed by plate member 74.

A vacuum receiving tube 98 is secured to plate member 74 at a through port therein to fluid couple the chamber 5 to the ambient atmosphere external the cap 62 and cap chamber 10. The tube 98 passes through and in fluid isolation relative to the chamber 10. The tube 98 passes through the cap 62 cover 102 and forms a vacuum tube (not shown) receiving nipple. The tube 98 is for releasably

attaching a vacuum device thereto to exhaust noxious fumes from the mixing chamber 5 during mixing of the cement.

The cover cap 62 comprises a thermoplastic molded cylindrical depending circular cylindrical skirt 100 formed one piece with generally flat disc-like cover 102. A vial 9 (Fig. 3) receiving tube 104 is formed in the cap 62 and defines a vial receiving conduit 106 in communication with chamber 10. A resilient circular cylindrical plug 108 selectively seals the conduit 106 after the vial is broken and the body 13 portion removed. The plug seals the chamber 10 to permit the liquid fumes to be efficiently evacuated from the mixing chamber 5 via tube 98. The cap circular cylindrical skirt 100 is preferably heat welded, e.g., ultrasonically, or otherwise permanently bonded to the cylinder 64 at shoulder 68.

In Fig. 3, the vial 9 head 11 is connected to body 13 by neck 15. The head is encased in a protective plastic cap 19.

In operation, the cement mixing device is supplied as illustrated in Fig. 1. The plug 108 is supplied separated from the device 2 as illustrated

or, in the alternative, may be supplied tethered to the cap 62, e.g., molded one piece therewith, with a connecting strap (not shown).

The caps 60 and 62 are interconnected as one permanent assembly and are disassembled from the housing 4 by unthreading the intermediate cap 60 from the housing 4. This opens the chamber 5 top to the ambient atmosphere as shown for example in the aforementioned copending application. The powder (not shown) is then poured into the chamber 5 followed by reattaching the unitary assembly of caps 60 and 62 to the housing 4.

In Fig. 3, the vial 9 is then inserted into the tube 104 conduit 106 of the assembled device with the powder in the chamber 5. The head 11 with the cap 19 attached is inserted first into the conduit 106 as shown. In this position the head at the cap tip 110 abuts the contoured surface 86 while being manually pushed into the trough 88.

In Fig. 4, the trough 88 contoured rounded surface forces the head 11 and cap 19 off of the vial 9 body 13 axis 112. Because the vial is frangible, it breaks due to the imposed transverse shear stress. The breakage may create small glass fragments (not

shown). The liquid cement component 7 flows out of the body 13 along the contoured surface 86. The chamber 10 substantially confines the fumes in cooperation with the vial in the port 106. The liquid 7 then passes through the port 90 via the passages 82 between the ribs 84 of the camming member 80. In the meantime, some liquid may remain in the vial head 11. Further insertion of the vial 9 along the axis 112 cams the head 11 upward as shown in Fig. 5 past the trough 88. This inverts the head 11 and permits the remaining liquid 7 in the head 11 to flow out via gravity into the passages 82.

Small glass fragments are captured by the filter 92 in the cap upper chamber 10 which forms a fragment receptacle. At the same time, the head 11 and head cap 19 also are captured in and remain in the chamber 10 isolated from the port 90 by the camming member ribs 84. The cap 62 and plate member 74 thus capture the head 11, cap 19 and glass fragments in the receptacle formed by the chamber 10. A vacuum source (not shown) is attached to tube 98 to evacuate fumes from the liquid in the mixing chamber 5. The vial 9 body 13 is then removed from the conduit 106 after the fumes have been evacuated.

In this embodiment, the chamber 10 is dimensioned to receive at least two vial heads 11 and their associated caps 19, Fig. 5. More or fewer heads 11 and caps 19 may be received in the chamber 10 as needed according to a given cement formulation. Preferably, two vials are employed with most formulations.

After the vials are emptied, the tube 104 conduit 106, Fig. 6, is closed with the plug 108, sealing the glass fragments including the vial heads 11 and associated caps 19 in the chamber 10. The plug 108 also seals the chamber 10 to preclude air from entering at conduit 106. This enhances the vacuum evacuation of the chambers 5 and 10. The used vial 9 may then be easily discarded with minimum danger of cutting to the user. The device 2, with the trapped glass fragments, is also discarded after the cement is dispensed in a single use.

In the alternative to the ribs 94 attaching the filter 92, filter 92 is preferably secured over the port 90 from within the chamber 10 or flush with the chamber 5 interior surface of the cap 60 member 74. This permits the bottom surface of the plate member 74 to be planar with no projections therefrom in the

mixing chamber. The paddles 14 can be provided with straight upper edges for abutting the plate member 74 bottom surface. This ensures good mixing of the powder and liquid cement components.

In an alternative embodiment, in Figs. 7 and 8, device 114 comprises a plastic molded housing 116 forming a bone cement mixing chamber 118. A pair of rotatable paddles 120 are in the chamber 118. The remainder of the housing 116 at the discharge end is the same as in the embodiment of Fig. 1. A one piece thermoplastic molded cap 122 having a threaded skirt is threaded to the housing 116.

The cap 122 comprises a threaded skirt cylinder 124 and a top cover plate member 126. A projection member 128 upstands from the plate member 126 and includes a boss 130 and an upstanding vial 9 receiving tube 132. The tube 132 has a tapered conical vial head 11 receiving bore 134 and a vial body 13 receiving inlet bore 136. A glass fragment filter 138 is secured flush with the interior surface of the plate member 126 in fluid communication with the chamber 118. A metal pin 140 is slidably received in a transverse bore of the boss 130 in communication with the tapered conical bore 134.

In operation, the powder is placed in the chamber 118 and the cap 122 is then installed on the housing 116 as shown. The vial 9 is placed inverted in the tube 132 bores 134 and 136. The head 11 tip is adjacent to the pin 140. To break the vial, the pin 140 is impacted against the head 11 tip shattering the tip. The shattered fragments are captured in the bore 134 between the filter 138 and body 13. The fragments are restrained from entering the chamber 118 by the filter 138. The liquid 7 in the vial 9 flows out by gravity into the chamber 118 through the port 137, which is between the bore 134 and the chamber 118, in the plate member 126. The vial body 13 may be retained in the tube 132 and discarded with the device 114 and entrapped glass fragments after the cement is mixed and dispensed in a single use operation. In the alternative, the bore may be plugged.

In a third embodiment, in Figs. 9-11, a cap 142 is attached to housing 116 as in the embodiment of Fig. 7. The mixing apparatus in the housing 116 chamber 118 is as described in the above embodiments. The cap 142 comprises a top cover plate member 144 attached to a threaded skirt cylinder 146 which

threads to the housing 116. A boss 148 upstands from the plate member and is integral one piece molded plastic material therewith.

A vial receiving tube 150 upstands from the boss 148 and has a vial receiving bore 152. The bore 152 terminates at a lower chamber 154. The chamber 154 is in communication with the housing chamber 118 via port 156. A glass fragment filter 158 is in port 156. The chamber 154 has a contoured vial camming lower surface 160. The surface 160 has a trough 162.

In operation, the vial 9 is inserted manually into the bore 152. The vial is then pushed against the camming surface 160 of the chamber 154 into and past the trough 162. The camming surface stresses the vial 9 at its neck 15 fracturing the vial. The vial 9 is pushed completely into the chamber 154 as far as it will go. This inverts the vial head 11, Fig. 11. The inverted vial head 11 then discharges its liquid 7 via gravity at the same time that the liquid 7 empties from the vial body 13. The liquid 7 flows into the housing chamber 118 as illustrated by the arrows.

The liquid flows through the port 156. The filter 158 traps the glass fragments in the chamber

154. The vial body 13 may remain with the device 142 in the tube 150 and discarded with the device 148 after the cement is mixed and dispensed.

In a further embodiment, Figs. 12-14, cap 170 is attached to housing 172 of mixing device 174 as described in the aforementioned embodiments. The cap cover plate 176 includes a vial receiving member 178. Member 178 includes a boss 180 and an upstanding vial receiving tube 182. The tube 182 has stepped bores 184, 185 in communication with a chamber 186. Bore 185 receives the body 13 and smaller diameter bore 184 receives the vial head 11.

A vial fracturing lever 188 is in chamber 186 and pivoted to boss 180 at pivot 190. The lever is adjacent to the vial head 11 as shown in Fig. 13. A glass fragment filter 192 is in port 194. The lever 188 is rotated against the received vial head 11 breaking the vial at the neck or fracturing the head 11. The liquid then flows by gravity into the chamber 118 through the filter 192 and port 194.

In Fig. 15, in the alternative, a vial fracturing device 192 comprises a preferably circular cylindrical in plan view thermoplastic molded housing 194. The housing 194 may be molded of multiple

pieces (not shown) and bonded to form a one piece integral construction. The device 192 is a separate structure from the cement mixing apparatus, serves to break the vial head 11 at the neck 15 and dispenses the emptied vial liquid into the cement mixing chamber.

A chamber 196 is formed in the housing 194. The chamber 196 is formed by the housing walls and by contoured floor surface 198. The floor surface 198 breaks the vial during insertion as described above in the Fig. 1 embodiment. The vial cap 19 impinges upon surface 198 when the cap and vial head 11 are in the chamber 196. A vial inlet tube 200 receives and partially encloses the head end portion of the vial 9. Also, as in the prior embodiment of Fig. 1, prevents fumes from escaping the chamber 196 when the vial is broken. The vial body 13 is closely received in the conduit 202 formed by tube 200.

The insertion axis 204 is oriented to cause the vial head and cap to interfere with the surface 198 during insertion. The surface 198 has a trough 206 in which is located a circular cylindrical discharge channel 208. Molded integral as one piece with the housing 194, or separately therefrom, is discharge

member 210. Member 210, if separate, is bonded to the housing in channel 208.

Member 210 forms a discharge port 212. A glass fragment and particle filter 214 is in and blocks the port 212. Filter 214 comprises material described in the prior embodiments.

In Figs. 15 and 16, the member 210 is formed with spaced ribs 216. The ribs 216 form a contoured surface 218 at the trough 206 that is continuous with the contoured surface 198. The spacing of the ribs 216 may be sufficiently close to retain larger glass fragments in chamber 196.

In operation, the vial 9 and its cap 19 are inserted into the conduit 202. As the vial engages surface 198, the contour thereof breaks the vial at its neck. The liquid in the vial then enters the trough 206 and flows from the chamber 196 through port 212. Not shown in this figure is the cement mixing chamber which receives the liquid from the port 212 in member 210. The member 210 forms a discharge nozzle which may be placed in a mating inlet port in the cover of the cement mixing apparatus (not shown in this figure). That cover

inlet port may be enclosed with a threaded cap or plug, for example.

In the alternative, the discharge port 212 may be in the side of the housing (shown in phantom in figure 15 at reference numeral 218). A cap (not shown) may close the nozzle 210 port 212 (or the port at 218). The inlet port of the cement mixing chamber may, in this case, also be in the side of the cement mixing chamber (not shown). The liquid is then poured from the vial breaking device by tipping the device to gravity feed the liquid contents.

There thus has been shown a bone cement and mixing device having a mixing chamber for mixing bone cement powder and liquid components. A glass vial receiving chamber is arranged to break the vial head from the vial body in response to insertion forces on the vial against a contoured camming surface in the vial receiving chamber. A discharge port with a glass fragment filter permits the liquid to flow to the mixing chamber while entrapping glass fragments. The receiving chamber also traps one or more of the vial heads or larger glass fragments that are broken free from the vial body.

Different devices are shown which may be used to break the vial to remove its liquid contents while entrapping the glass fragments.

It will occur to one of ordinary skill that various modifications may be made to the disclosed embodiments. It is intended that the disclosed embodiments are given by way of illustration and not limitation. The invention is defined by the appended claims.

What is claimed is:

1. A vial fracturing device for use with a bone cement mixing and dispensing apparatus for mixing liquid with powder cement components, the liquid tending to emit noxious fumes, the apparatus having a component mixing chamber and mixed cement dispensing means coupled to the mixing chamber, the mixing chamber for receiving the powder and the liquid components, the liquid being supplied in a frangible glass vial, the vial when fractured tending to produce undesirable glass fragments, the device comprising:

a housing forming a liquid receiving chamber having a discharge port arranged for fluid communication with the mixing chamber;

vial receiving means coupled to the housing for receiving and enclosing at least a portion of the vial and for permitting the liquid to flow to and through the discharge port into the mixing chamber from the received vial when fractured; and

vial fracturing means coupled to the housing and to the liquid receiving chamber for fracturing said received enclosed vial portion.

2. The device of claim 1 including means coupled to the vial receiving means for substantially confining said liquid fumes to said liquid receiving chamber.

3. The device of claim 1 including filter means coupled to the housing for preventing said glass fragments from passing through said discharge port.

4. The device of claim 1 wherein the vial receiving means has a vial inlet conduit coupled to said liquid receiving chamber, said liquid receiving chamber for further receiving the vial portion, said fracturing means including contoured surface means in said receiving chamber forming a cam surface for fracturing said vial upon insertion of the vial into said inlet conduit and upon engagement of said vial portion against said surface.

5. The device of claim 4 wherein said vial has a body connected to a head by a neck, said cam surface for fracturing the neck during insertion to separate the head from the body.

6. The device of claim 5 wherein said liquid receiving chamber provides a receptacle for said separated head and fragments.

7. The device of claim 5 wherein the vial receiving conduit defines a vial insertion axis, said cam surface being inclined relative to said axis for forcing the head off said axis relative to the body at said neck during the insertion.

8. The device of claim 5 wherein said liquid receiving chamber provides a receptacle for a plurality of said heads.

9. The device of claim 5 wherein the surface means comprises a plurality of spaced ribs forming a fluid conduit into said mixing chamber.

10. The device of claim 5 including filter means coupled to the discharge port for precluding discharging the fragments.

11. The device of claim 1 further including the mixing apparatus and including a cover releasably

secured to said apparatus for enclosing the apparatus chamber to permit said powder to be inserted in said mixing chamber, said cover including said device integral therewith and a filter for filtering said glass fragments from entering the apparatus chamber.

12. The device of claim 1 further including the apparatus and wherein said mixing chamber comprises a housing and a cap releaseably secured to the housing, said cap comprising said device, said liquid receiving chamber having a vial camming surface for engaging and fracturing the vial while the vial is inserted into the liquid receiving chamber from said vial receiving means.

13. The device of claim 12 wherein the vial has a body and a head connected to the body by a neck, said camming surface being oriented so that liquid flows from the body and from the head via gravity after said fracturing.

14. The device of claim 1 wherein said fracturing means includes means movably coupled to the housing

in the liquid receiving chamber for fracturing the received vial by stress engagement against the vial.

15. The device of claim 14 wherein the fracturing means includes at least one of a pin and lever.

16. The device of claim 1 further including the apparatus, said apparatus including mixed cement feed means in selective fluid communication with said mixing chamber by an axially displaceable sleeve forming a cement feed conduit and sleeve displacement means rotatably coupled to the housing and having a helical channel engaged with and for displacing the sleeve in response to rotation of the displacement means.

17. A bone cement mixing apparatus comprising:

a first housing forming a bone cement mixing chamber;

means coupled to the housing for mixing liquid and powder bone cement components in the chamber;

cover means releasably secured to the housing for providing a cement powder receiving port to said chamber, said cover means including a contoured

surface, an opening in the cover means for providing fluid communication between said surface and said mixing chamber; and

means adjacent to said contoured surface to form a liquid cement component receiving chamber, said cover means having a frangible vial receiving port in communication with said liquid component receiving chamber, said vial for supplying said liquid component, said port and surface cooperating for fracturing the vial upon insertion against the surface.

18. The device of claim 17 wherein the means adjacent to the contoured surface comprises a second housing secured to the first housing and forming a liquid component receiving chamber therebetween, said liquid component receiving chamber for receiving fractured vial fragments.

19. A bone cement mixing device comprising:

a housing forming a bone cement mixing chamber;

means coupled to the housing for mixing liquid and powder bone cement components in the chamber;

cover means releasably secured to the housing for providing a cement powder component receiving port, said cover means having a second chamber for receiving at least a portion of the vial and the liquid component from the vial, an opening in the cover means for providing fluid communication between said second chamber and said mixing chamber; and

means for fracturing the vial portion in said second chamber.

20. The device of claim 19 wherein the means for fracturing is selected from the group consisting of a contoured surface, a pin and a movable lever.

21. The device of claim 19 wherein the cover means comprises an intermediate cap enclosing the mixing chamber and a cover cap over the intermediate cap forming said second chamber.

22. The device of claim 21 wherein the means for fracturing comprises a contoured surface in the cover means chamber and a port for receiving the at least a portion of the vial cooperating with the surface for

fracturing the vial upon insertion of the vial into the port.

23. A bone cement mixing and dispensing apparatus for mixing liquid with powder cement components comprising:

a housing having a component mixing chamber for receiving said powder and said liquid components; and

mixed cement dispensing means coupled in selective fluid communication with said mixing chamber;

said dispensing means including an axially displaceable sleeve forming a cement feed conduit and sleeve displacement means rotatably coupled to the housing and having a helical channel engaged with and for displacing the sleeve in response to rotation of the displacement means.

FIG. 1

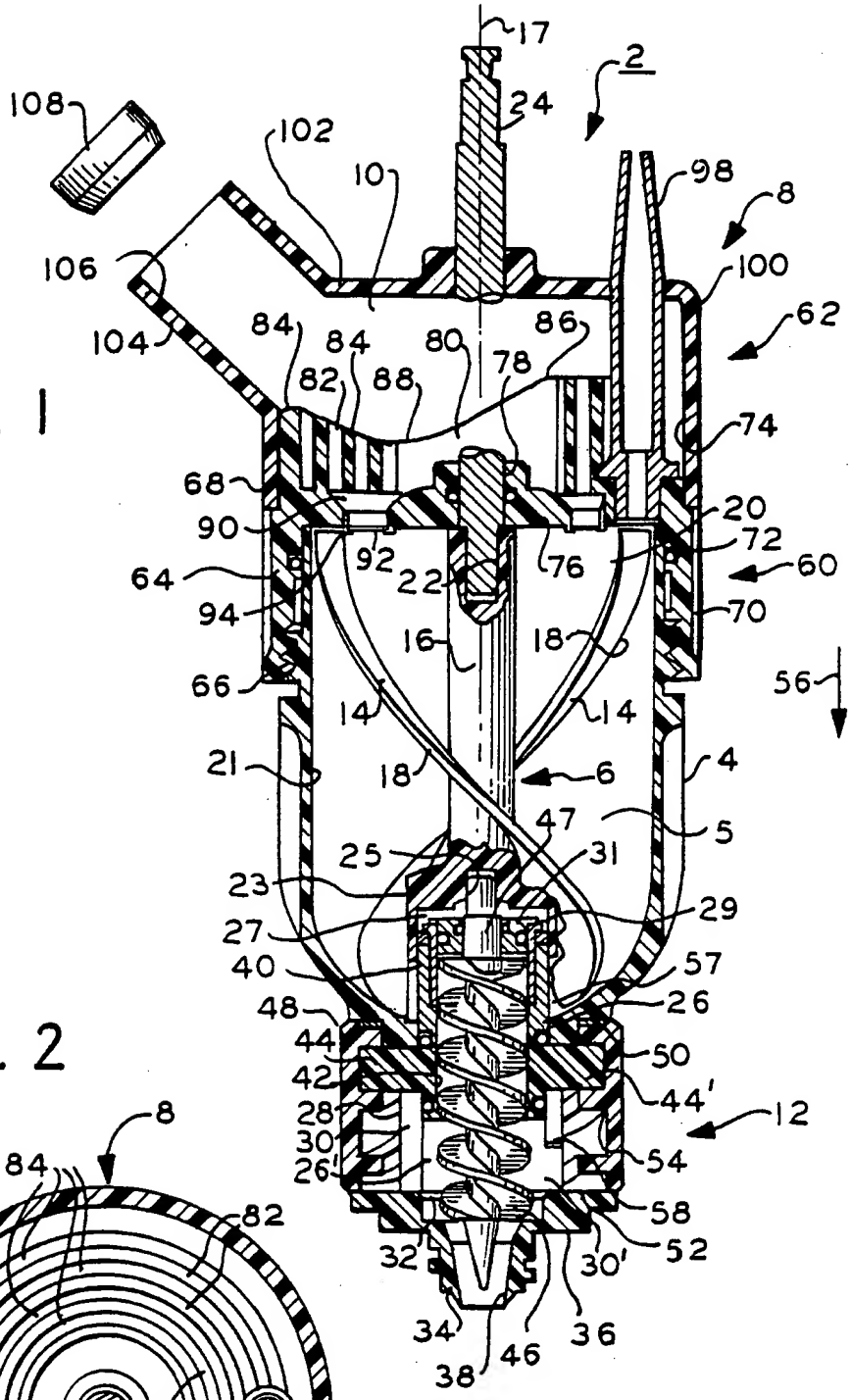
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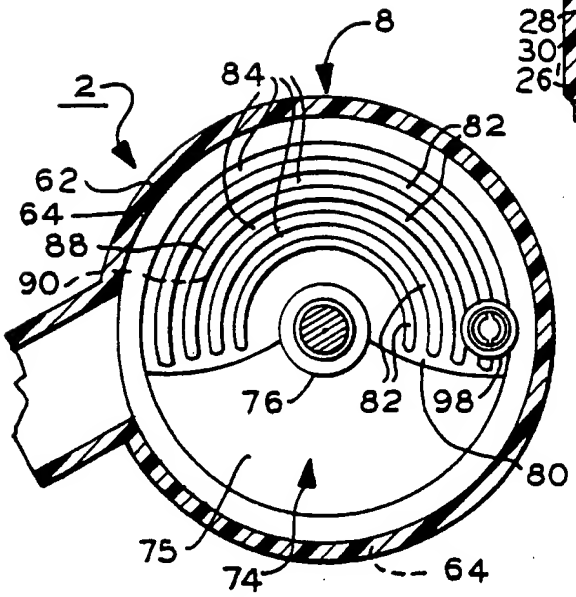
FIG. 2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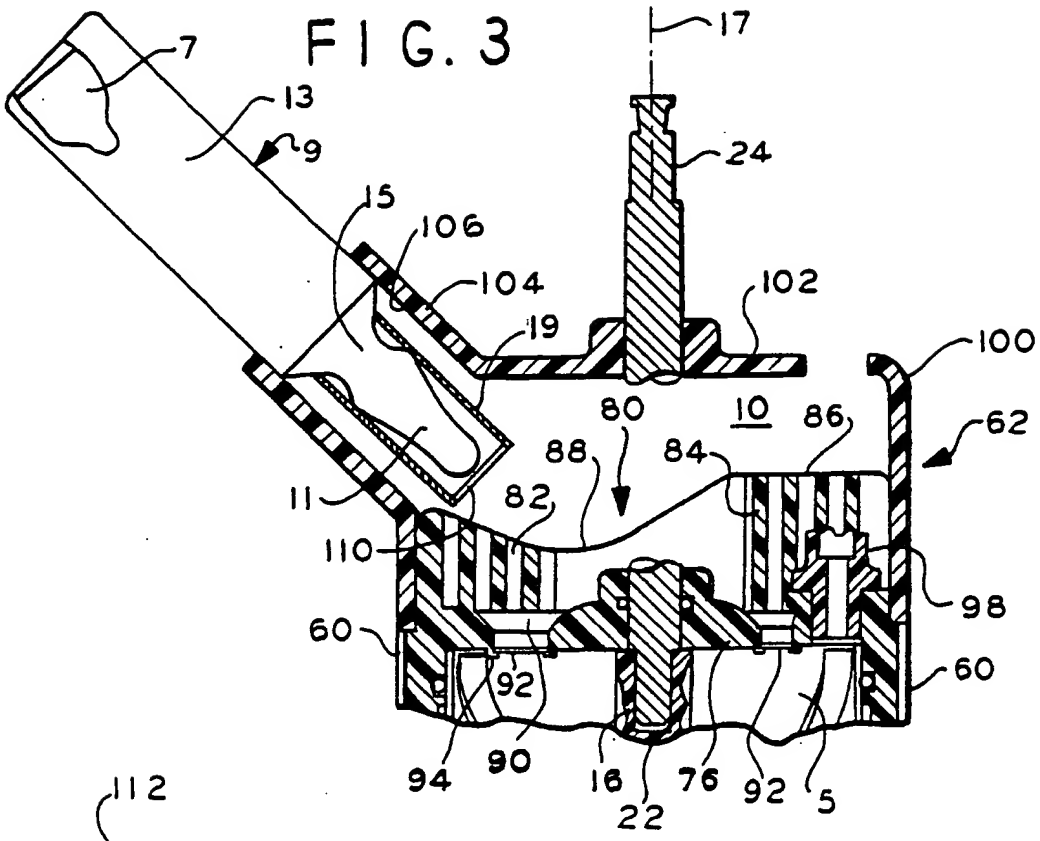
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FIG. 4

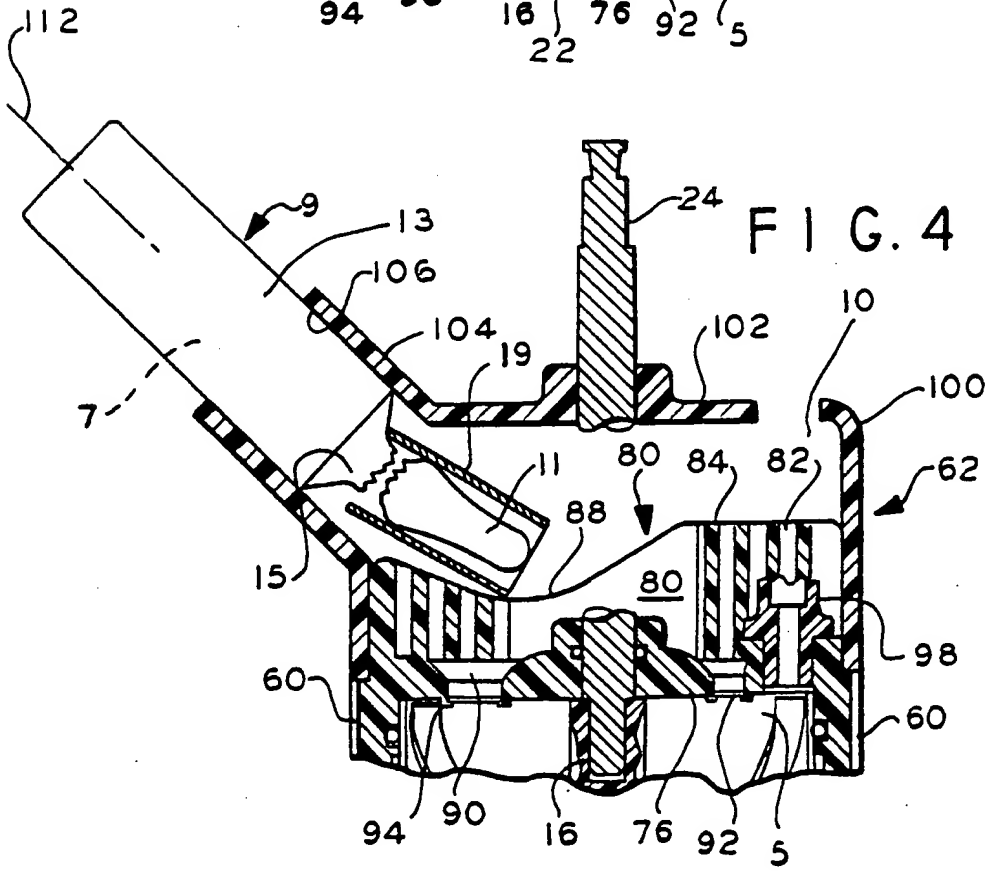
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FIG. 5

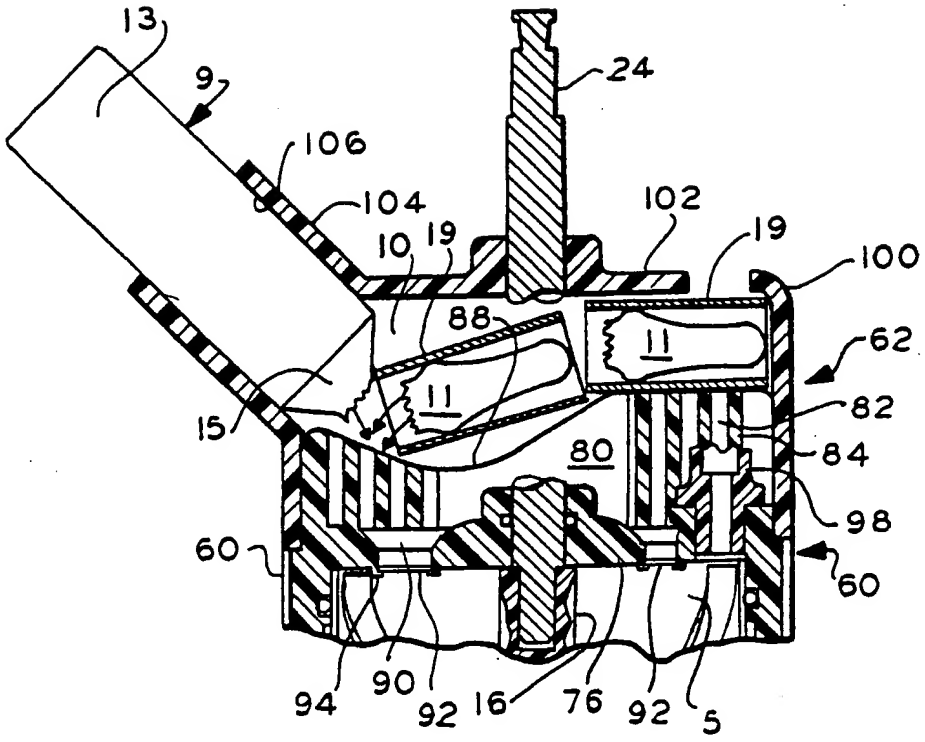
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FIG. 6

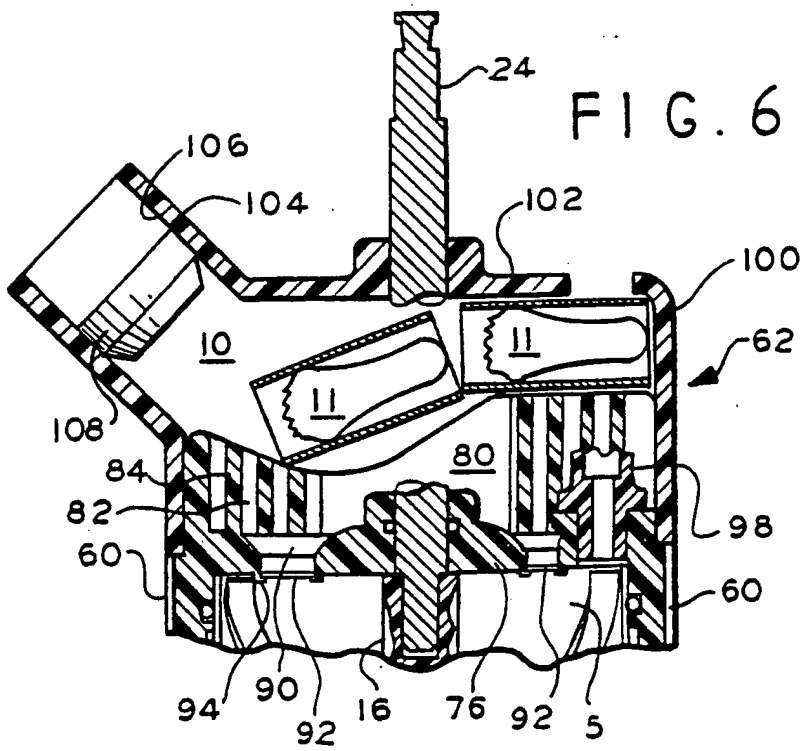
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FIG. 7

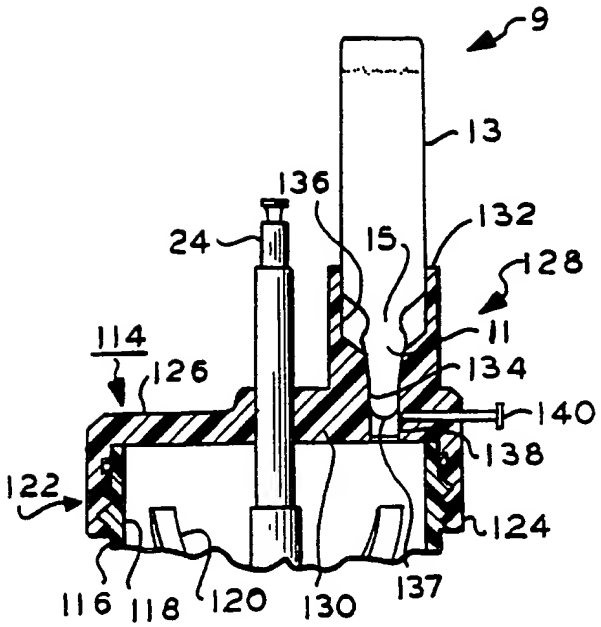


FIG. 8

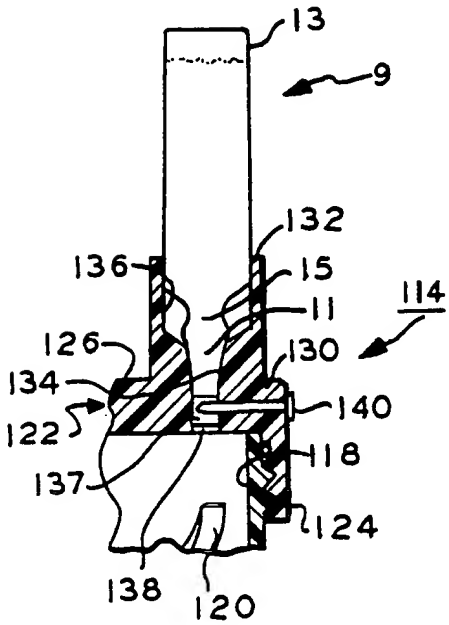


FIG. 9

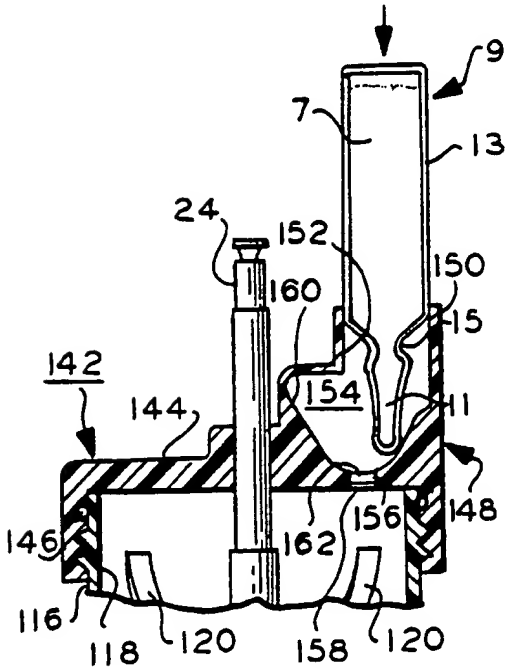


FIG. 10

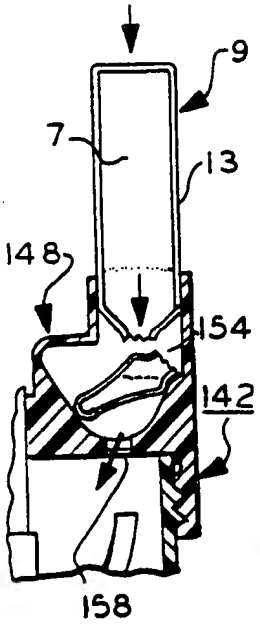


FIG. 11

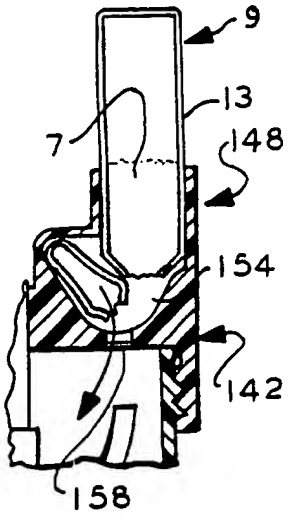


FIG. 12

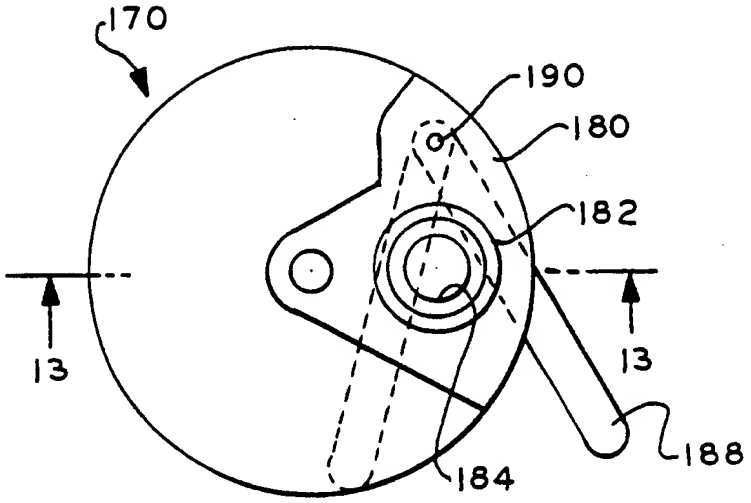


FIG. 13

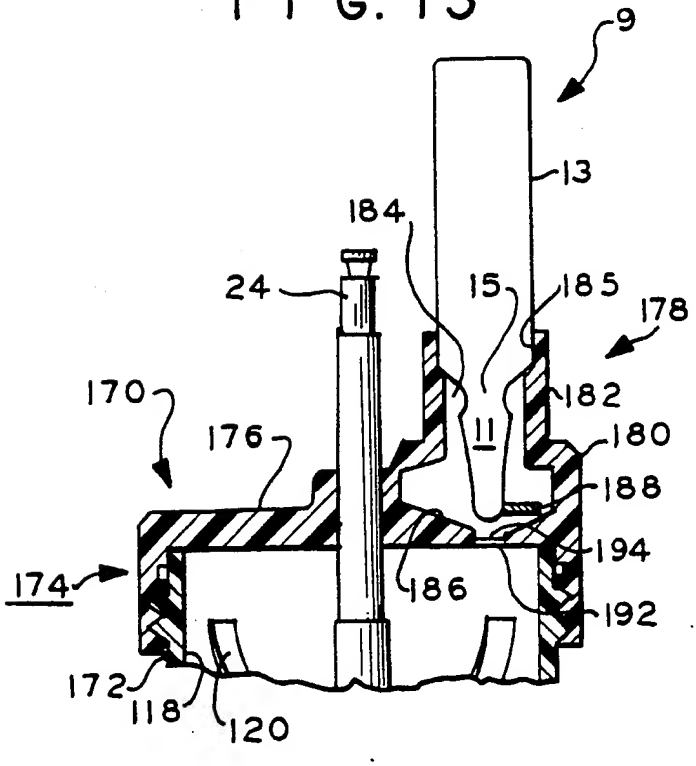
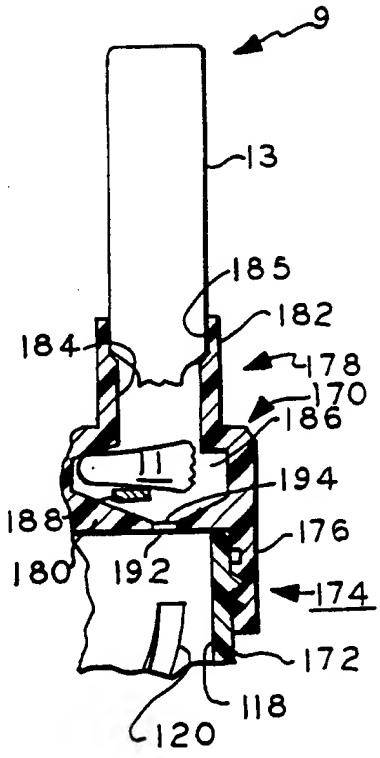


FIG. 14



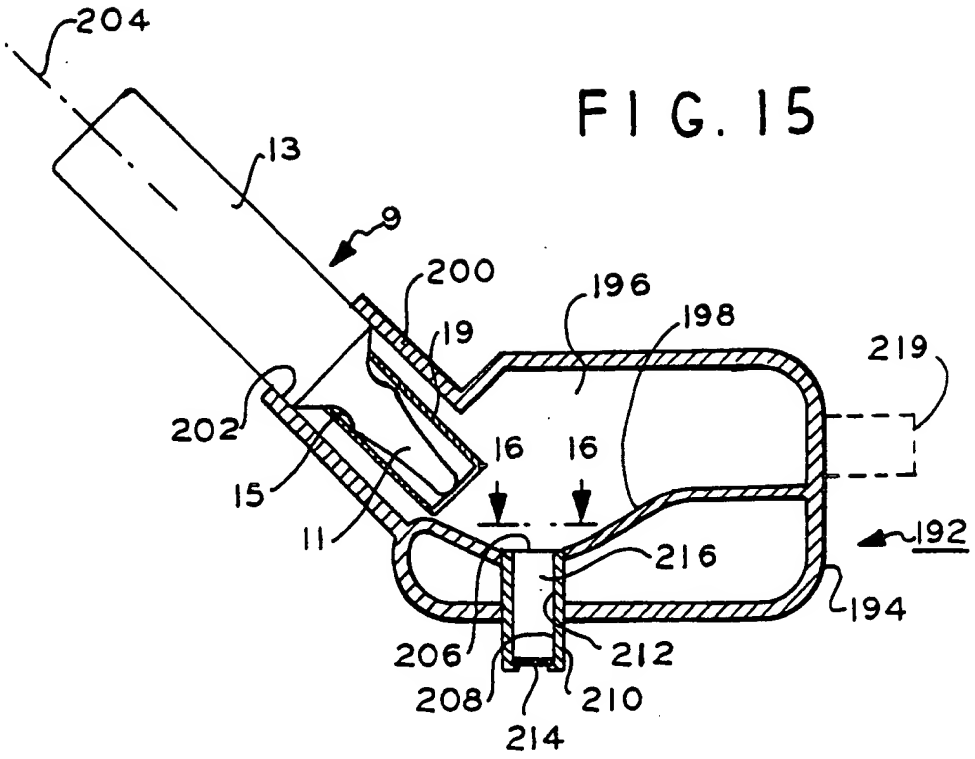

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FIG. 15

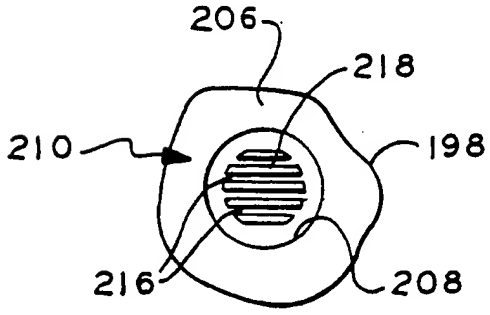
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FIG. 16

INTERNATIONAL SEARCH REPORT

Ir ational Application No
PCT/US 99/01185

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/46 B01F13/00 B01F15/02 A61J1/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y A	DE 29 21 565 A (GALIA) 4 December 1980 see the whole document ---	1,4-7, 14,15, 17-22 2,3,10, 16,23 12
Y	WO 93 10892 A (SUMMIT MEDICAL) 10 June 1993 see page 5, line 19 - page 6, line 2; claim 17; figures ---	2
Y A	US 5 306 277 A (BRYANT) 26 April 1994 see the whole document ---	3,10 1,11
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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
15 June 1999	22/06/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Klein, C

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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